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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,571	04/01/2004	B. Ron Johnson	15070.6.2	1232
7590 11/28/2007				
John M. Guynn WORKMAN NYDEGGER 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111				
			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,571

Applicant(s)

JOHNSON, B. RON

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 25-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/30/04, 2/22/06, 3/27/06, 6/19/06, 5/21/07.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II in the reply filed on September 6, 2007 is acknowledged. The traversal is on the ground(s) that the amendment to claim 30 renders claims 30-35 within the scope of the elected invention. This is not found persuasive because claim 30 is drawn to a method of treating a herpes virus-induced disordered tissue such as a cold sore and the amendment to claim 30 which adds a proviso drawn to "smallpox lesions" lacks antecedent basis. Applicant traverses the restriction between groups II and III because Applicant states that claim 14 is generic to claims 25-35 because smallpox lesions and lesions caused by a herpes virus are merely species of "pathogen-induced disordered tissue." This is not found persuasive because the product as claimed can be used in a materially different process of using that product. U.S. Patent No. 3,620,807 describes a method for imparting softness to textiles without yellowing employing a fabric softening quaternary ammonium salt (see abstract). Further the Group I invention is drawn to a composition comprising at least one quaternary ammonium halide in a carrier and the Groups II and III inventions are drawn to a method of treating an infection/smallpox infection on the skin with an organohalide. This is an entirely different search category. The Group IV invention is unrelated because it is drawn to a method of treating a herpes disordered tissue comprising employing an anti-infective agent. This broad search category is not related to the Groups I-III inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 6, 2007.

Claims 1-13 and 30-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 6, 2007.

Information Disclosure Statement

The information disclosure statement filed June 30, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant has indicated that these foreign and non-patent literature references have been previously cited in a parent application. None of these references have been found with the exception of French Patent Application EP 0 478 445 A1 that was found in application number 10/200897.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "rapidly diffusing" in claim 14 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "slowly diffused" a given value can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "rapidly diffusing" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Claims 15-24 are indefinite to the extent that they read on the rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Beauchamp et al. U.S. Patent No. 5,753,270 A.

Beauchamp et al. teach a composition for treatment of skin afflicted diseases such as cold sores, fever blisters, genital herpes, psoriasis, acne or eczema and the like (column 3, lines 10-13) comprising applying to the skin an aqueous solvent system (column 3, lines 50-53) that comprises an antiseptic such as an alcohol and a quaternary ammonium antiseptic compound (column 4, lines 4-33). The alcohol can be isopropyl alcohol or the like, in water and the quaternary ammonium antiseptic compound may be benzalkonium chloride in an organic skin penetrating solvent (column 5, lines 25-35). There does not appear to be a recitation of a penetration inhibiting compound in the composition disclosed in Beauchamp et al., thus it is substantially free of penetration inhibiting components. Regarding the limitation of claim 14 drawn to penetration of the skin in a rapid manner so as to form a reservoir of the treatment composition within the disordered tissue without rapidly diffusing beyond the disordered tissue, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34). It does not recite diffusion beyond the disordered tissue. Regarding the manner of application, it is generally understood that "apply liberally" would imply that the formulation is rubbed on the affected area (column 5, lines 56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beauchamp et al. U.S. Patent No. 5,753,270 A and Remington's Pharmaceutical Sciences, 1975.

Beauchamp et al. teach a composition for treatment of skin afflicted diseases such as cold sores, fever blisters, genital herpes, psoriasis, acne or eczema and the like (column 3, lines 10-13) comprising applying to the skin an aqueous solvent system (column 3, lines 50-53) that comprises an antiseptic such as an alcohol and a quaternary ammonium antiseptic compound (column 4, lines 4-33). The alcohol can be isopropyl alcohol or the like, in water and the quaternary ammonium antiseptic compound may be benzalkonium chloride in an organic skin penetrating solvent (column 5, lines 25-35). There does not appear to be a recitation of a penetration

inhibiting compound in the composition disclosed in Beauchamp et al., thus it is substantially free of penetration inhibiting components. Regarding the limitation of claim 14 drawn to penetration of the skin in a rapid manner so as to form a reservoir of the treatment composition within the disordered tissue without rapidly diffusing beyond the disordered tissue, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34).

Beauchamp et al. does not disclose the method wherein the carrier is 70% isopropyl alcohol. Beauchamp however, discloses that the solvent is combined with water in an amount in the range exceeding about 50% (column 5, lines 25-26). This amount overlaps with 70%.

Beauchamp et al. does not disclose the method wherein the composition is no longer visible after about 2 minutes, however, all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art;

whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Regarding the limitation of claim 22 wherein the method of treatment is by applicant of the composition by vigorously agitating the disordered tissue, Remington's Pharmaceutical Sciences, 1975, recites that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to vigorously agitate the disordered tissue when applying the composition motivated by the teaching of Beauchamp et al. that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph).

Regarding claims 23 and 24 drawn to treatment of disordered tissue caused by smallpox virus and anthrax bacteria; Beauchamp et al. teach the destruction of **viral** and **bacterial** cells which are the source of the diseased skin condition by topical application to the skin (column 3, lines 3-34). The prior art showed destruction of viral and bacterial cells by topical application of the composition of an organohalide such as benzalkonium chloride and isopropyl alcohol in water. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the smallpox viral cells or the anthrax bacterial cells the predictable result of the destruction of the viral and bacterial cells.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

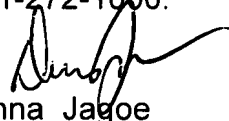
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe
Patent Examiner
Art Unit 1614

November 26, 2007